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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,982	03/22/2001	Frank R. Miele	VWAVE.001CP2	7628
27299	7590	06/08/2007		
GAZDZINSKI & ASSOCIATES 11440 WEST BERNARDO COURT, SUITE 375 SAN DIEGO, CA 92127			EXAMINER JAWORSKI, FRANCIS J	
			ART UNIT	PAPER NUMBER
			3768	
			MAIL DATE	DELIVERY MODE
			06/08/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/815,982

Applicant(s)

MIELE ET AL

Examiner

Jaworski Francis J.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-14, 19-24, 36, 38 and 41-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6, 8, 10 - 14, 19-24, 36, 38, 41 - 44, 49 - 50 and 53 - 55 is/are allowed.
- 6) ☒ Claim(s) 46, 51-52 and 56 - 58 is/are rejected.
- 7) ☒ Claim(s) 47 - 48 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Specification***

The disclosure is objected to because of the following informalities: page 4 line 6 " imprecise " to -- precise -- (?); status 09/815080 should be updated since it is now US Pat. No. 7048691.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 46, 51 - 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al (US5280787). Wilson et al (US5280787) teaches in Fig. 2B elements

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33 and 34 and discussion thereof a technique for using A-mode ultrasound from the B-mode image and the reduced echo signature of less echogenic vessel blood to determine vessel wall location by local minimum identification, see col. 7 lines 20 – 54, and although in a non-tonometric environment, at least an applanation sufficient to flatten the skin to avoid an air interface at the contact surface would occur, with the probe handle being an applanation means.

Claims 56 – 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butterfield et al (US5273046, of record in the IDS of 1/29/02) in view of Wilson et al and Eckerle (US4802488).

Butterfield et al in col. 15 when detailing forming an applanation index includes the teaching that ultrasound may be used to detect applanation towards the index. Wilson et al would evidence that such vessel wall locating would include A-scan data as a modality for the detecting (within the applicability limits noted immediately above and also below). Since Eckerle mentioned in Butterfield et al col. 2 teaches that the applanation positioning and tonometry proceed in relation to a local minimum detection phenomenon and since claim 56 does not assign the claimed local minimum phenomenon to either sensor type, the rejection argument poses that the base claim is rejectable on a known applanation technique where a pressure-sensor-based local minimum as in Eckerle '488 is used together with at least some cognizance that a vessel wall displacement can be measured by acoustic reflectivity level where nearby blood is at a lower reflectivity level as per Wilson et al, in an overall applanation tomometry system as in Butterfield et al.

### ***Allowable Subject Matter***

Claims 1 – 6, 8, 10 – 14, 19 – 24, 36, 38, 41 – 44, 49 - 50, 53 - 55 are allowed.

Claims 47 – 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### **Response to Arguments**

With respect to ultrasound in relation to artery wall location per se where active energy is transmitted into the vessel to determine where it is based on A-mode information, Wilson et al uses both dimensions available within B-mode from individual A-scan data, in the context of a local minimum insofar as blood is less reflective than tissue wall. The digression is inter alia that no pressure measurement or pressure sensor placement is contemplated, and 'applanation pressure' would be only just sufficient to flatten the skin against surface echo artifact. Hence this first residual impediment to completing a patentable claim language set remains.

With respect to combined active (meaning energy emitting as opposed to 'active') ultrasound and passive pressure sensor use together with artery location identification, since Butterfield obliquely mentions in col. 15 that ultrasound displacement measurement may be used to provide an applanation index, the teaching of Wilson et al supplements solely in evidencing that A-mode can detect a vessel edge by generically using the higher wall reflectivity in relation to the local minimum of blood

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reflectivity (without literal incorporation of the latter in toto, since its en bloc relationship to applanation is limited as immediately above), and since Eckerle '488 teaches that a local minimum phenomenon was known in relation to applanation tonometry measurements with pressure sensors, the three-reference combination is considered to fairly represent a second residual impediment to allowance of a limited number of claims.

Vilkomerson (US5669388) is directed to automatic transducer placement by active ultrasound array element energization and returned echo energy analysis however the array elements are of Doppler diffraction/non-diffraction type and placement is non-tonometric and directed to flow measurement by maximum pulse identification.

Tsubata (US6447456) is directed to use of an active ultrasound array 11,21,11',21' together with an energy intensity comparison stage 75 however the latter is associated with control logic operating for noise immunity purposes.

Nissala et al (US6443905) teaches use of a local minimum in pressure pulse amplitude measurement as a statistical parameter associated with measurement quality assessment.

Eckerle (US4269193) , Eckerle et al(US5065765) Fig. 3 pertain to a passive pressure sensor-based applanation tonometry system and method inclusive of finding a local signal minimum underlying the artery being measured.

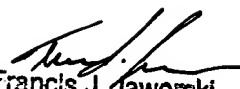
This action is NOT made final however the case should be prepared for final action.

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Any inquiry concerning this communication should be directed to Jaworski  
Francis J. at telephone number 571-272-4738.

FJJ:fjj

060507



Francis J. Jaworski  
Primary Examiner